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Cost of Opioid-Treated Chronic Low Back Pain: Findings from a Pilot Randomized Controlled Trial of Mindfulness Meditation-Based Intervention

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Abstract

Objective—Opioid-treated chronic low back pain (CLBP) is debilitating, costly and often refractory to existing treatments. This secondary analysis aims to pilot-test the hypothesis that mindfulness meditation (MM) can reduce economic burden related to opioid-treated CLBP.

Design—26-week unblinded pilot randomized controlled trial, comparing MM, adjunctive to usual-care, to usual care alone.

Setting—Outpatient

Participants—Thirty-five adults with opioid-treated CLBP (≥ 30 morphine-equivalent mg/day) for 3+ months enrolled; none withdrew.

Intervention—8 weekly therapist-led MM sessions and at-home practice.

Outcome Measures—Costs related to self-reported healthcare utilization, medication use (direct costs), lost productivity (indirect costs), and total costs (direct+indirect costs) were

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[ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT01775995) # NCT01775995

Conflict of Interest

Otherwise, the authors have no ownership interest or affiliation with any commercial or for-profit company or program that would create a conflict of interest.

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calculated for 6-month pre- and post-enrollment periods and compared within and between the groups.

Results—Participants (21 MM; 14 control) were 20% men, age 51.8 ± 9.7 years, with severe disability, opioid dose of 148.3 ± 129.2 morphine-equivalent mg/day, and individual annual income of $\$18,291 \pm \$19,345$. At baseline, total costs were estimated at $\$15,497 \pm 13,677$ (direct: $\$10,635 \pm 9,897$; indirect: $\$4,862 \pm 7,298$) per participant. Although MM group participants, compared to controls, reduced their pain severity ratings and pain sensitivity to heat-stimuli ($p < 0.05$), no statistically significant within-group changes or between-group differences in direct and indirect costs were noted.

Conclusions—Adults with opioid-treated CLBP experience a high burden of disability despite the high costs of treatment. Although this pilot study did not show a statistically significant impact of MM on costs related to opioid-treated CLBP, MM can improve clinical outcomes and should be assessed in a larger trial with long-term follow-up.

Keywords

mindfulness meditation; chronic low back pain; opioids; economic evaluation

INTRODUCTION

The U.S. Healthcare System is the most expensive in the world.¹ Americans are also the highest consumers of prescription medications.² Despite high spending, the U.S. was ranked last among 11 industrialized countries when comparing quality, access, efficiency of healthcare, and health indicators.¹

Low back pain (LBP) affects 80% of U.S. adults in their lifetime.³ Chronic LBP (CLBP) affects 15-20% of LBP sufferers,⁴ yet it incurs 90% of total LBP-related costs estimated at \$84.1-\$624.8 billion annually.⁴⁻⁶ A 2008 analysis of a nationally-representative insurance claims database showed greater annual direct medical costs of patients with CLBP (\$8,386) compared to non-CLBP controls (\$3,607).³ Indirect costs due to lost productivity are estimated to be even more substantial.^{5,7}

Severe refractory CLBP is the most common chronic non-cancer pain treated with long-term opioids.⁸ Opioid therapy is controversial in CLBP and associated with dose-dependent harms, including hyperalgesia, addiction, and overdose death.⁸⁻¹⁰ Providing patients with new, cost-effective and safe therapy options for opioid-treated CLBP could lead to an increase in value of medical spending that the U.S. desperately needs and decrease patients' reliance on opioids.

Mindfulness meditation (MM) has been used to treat chronic pain for decades and recent studies support its potential for opioid-treated chronic pain.¹¹⁻¹⁶ Our 26-week pilot randomized-controlled trial (RCT, N=35) showed that MM was associated with reduced pain severity ($p < 0.05$) and decreased sensitivity to heat-pain stimuli ($p < 0.05$) among adults with disabling CLBP treated, on average, with a high-dose opioid therapy.¹⁵ In addition, the MM intervention was found to be safe, feasible, and highly acceptable.¹⁶

Little is known about MM's effects on costs related to this health condition. Therefore, we performed a secondary cost-analysis of data from our pilot RCT, which focused on the acceptability, feasibility and efficacy assessment of the MM intervention.^{15,16} We hypothesized that MM, in addition to safely improving health outcomes, can also reduce costs in opioid-treated CLBP.

METHODS

Design

Data were derived from a 26-week pilot parallel-arm RCT of MM intervention, adjunctive to usual care (MM group, N=21), compared to usual care alone (wait-list control, N=14) among adults with opioid-treated CLBP. The study was approved by the Institutional Review Board and registered with [ClinicalTrials.gov](https://www.clinicaltrials.gov). Details of the methods, and efficacy and feasibility results were published elsewhere.¹⁵⁻¹⁷ This paper focuses on secondary cost-analysis findings.

Participants

Potential participants were recruited from several local health systems. They were 21 years or older, diagnosed with CLBP and treated with opioids 30 mg/day of morphine-equivalent dosage (MED) for 3+ months.^{15,17} All 35 enrolled participants completed baseline and at least one follow-up assessment (34 completed an 8 week; 33 completed a 26-week follow-up), providing data for the analysis.¹⁵ No participant withdrew from the study. The CONSORT study flow diagram is presented elsewhere.¹⁵

As previously published, participants were 51.8±9.7 years old (20% male, 20% non-Caucasian) and reported severe disability (66.7±11.4%; Oswestry Disability Index¹⁸⁻²⁰), averaged pain severity of 5.8±1.4 (0-10 rating scale; Brief Pain Inventory²¹) and high daily opioid dose (148.3±129.2 mg/day MED).^{15,17} They earned \$18,291±\$19,345 annually, with 34% reporting an individual income greater than \$15,000 and 77% receiving social security/disability benefits.¹⁷ Over the 26-week follow-up period, the MM group participants, compared to the controls, reported a reduction in pain severity ratings (p=0.045) and showed a decreased sensitivity to noxious heat stimuli (p<0.05).¹⁵

Setting and Procedures

Sample size for this pilot study was convenience-based. Participants were enrolled, completed baseline assessments, and then were randomized.¹⁵ Randomization envelopes were prepared by the study statistician to account for up to 50 enrolled participants (1:1 randomization ratio); since we enrolled 35 participants within a designated recruitment/enrollment period, this led to unequal group sizes. Follow-up assessments occurred at 8 weeks (post-intervention; F1) and 26-weeks (F2) post-entry.

MM Intervention

All participants continued usual care for opioid-treated CLBP²² through their regular providers. In addition, the MM group received the MM intervention (eight weekly 2-hour group sessions, led by two trained and experienced therapists, and at-home MM practice at

least 6 days/week during the whole study), described elsewhere.^{15,16} The MM intervention was patterned after established curricula^{23–25} and tailored to meet the psychophysical needs of patients with opioid-treated CLBP.

Outcome Measures

All measures relied on self-report.

Healthcare utilization and productivity loss data were collected with a study team-developed survey based on expert recommendations.²⁶ The survey inquired about the “past 6 months” at baseline, the “past 8 weeks” at F1, and the “past 18 weeks” at F2, yielding 6 months of pre-enrollment and 6 months of post-enrollment data. Healthcare utilization was measured by the number of visits, regardless of the reason, to the emergency department (ED), urgent care, primary care, and outpatient mental health care, and the number of days of hospitalization (overnight stay). Productivity loss was quantified as the number of missed work days and the number of missed school/housework days (missed household chores and responsibilities) due to being sick, injured or not feeling well.

Medication use (average daily use, past 30 days) was measured by the study team-developed medication survey, and verified against the medication bottle information.^{15,17} The Timeline Followback (TLFB) method^{27,28} was used to collect data on the daily use of prescription-based opioids for the “past 28 days” to enable calculation of a MED/day.

Total costs associated with opioid-treated CLBP were defined as a sum of direct costs (healthcare utilization, medications) and indirect costs (lost productivity from missed work and/or school/housework) in the prior 6 months.

Healthcare Utilization Costs—Hospitalization, ED, and urgent care visit costs were estimated using the state Price Point System-data for 2013.²⁹ Average daily hospital inpatient charge (\$1,722) was based on an “Other back/neck disorders, fractures, and injuries, no surgery” diagnosis.³⁰ ED visit cost (\$945) was based on “Neck/Back Sprains & Strains” and “Spinal Disorders” diagnoses.³¹ Hospital-based urgent care charge (\$257) estimated the cost of using urgent care.^{31,32}

Medication Costs—The average quantity of each medication taken by participants (past month) was estimated from the medication survey for non-opioid medications and the TLFB for opioids. Medication use and related costs were prorated from “past month” to “past 6 months” at baseline and proportionately during the follow-up to estimate medication costs for 6 months pre- and 6 months post-enrollment.

Medications were categorized as: A) opioids; B) non-opioid analgesics and medications with pain-modulating properties; C) bowel regimen medications; and D) other medications, including vitamins, herbal preparations and other supplements, and topicals (Table 1).

Price quotes for a monthly supply of each specific medication (brand-name versus generic) were obtained in July and August 2014 using the following sources and protocol: a) primary source: www.rxpricequotes.com; using the local zip code;³³ b) secondary source:

www.drugs.com;³⁴ c) tertiary source: www.walgreens.com;³⁵ d) quotes for medications with an unlisted price were obtained by calling the local Walgreens pharmacy. In addition, for non-prescription medications, the least expensive preparation was selected; when the exact pricing was not possible to calculate, a bottle size that best accommodated the participant's monthly use was applied; the average of listed price ranges was used to estimate a monthly medication cost; and, if the calculation of the average monthly quantity yielded a fraction, this number was rounded up to the next whole number.

Productivity Loss—The cost associated with productivity loss was calculated by multiplying the number of missed work or school/housework days by the estimated cost of each lost-productivity day. Cost of a missed work day (\$162.72) was based on a state-specific average daily wage, calculated by averaging the 2013 state-specific daily wages across all occupations listed by the U.S. Department of Labor Bureau of Labor Statistics.³⁶ Cost of a missed school/housework day (\$58) was estimated based on the assumption of an 8 hour day of productivity, valued at the 2013 federal minimum wage of \$7.25/hour.³⁷

Statistical Analyses

IBM SPSS statistics 22 software was used for analyses. The Related-Samples Wilcoxon Signed Rank Test evaluated within-group changes over time. The Independent Samples Mann-Whitney U Test evaluated between-group differences at each time point and differences in longitudinal change in a given variable. Cohen's d effect size evaluated the magnitude of between-group differences in longitudinal change.³⁸ Statistical significance was set at a two-tailed $p < 0.05$. Results were presented as a mean ($\pm$ standard deviation, SD) unless otherwise noted.

RESULTS

Baseline Characteristics

Direct and Indirect Costs (Table 1)—Pre-enrollment (past 6 months), participants reported 10.2 ± 11.1 outpatient visits, missed 12.3 ± 42.4 days of work and 49.4 ± 64.8 days of school/housework. They used 1.8 ± 0.7 different opioid and 2.9 ± 1.7 non-opioid medications for pain relief, and 7.9 ± 5.1 medications for conditions other than pain or constipation. The average direct and indirect costs totaled $\$15,497 \pm \$13,677$. Medication costs comprised 60% of direct costs, exceeding healthcare utilization cost, for which hospitalization yielded the highest cost. Primary care visits were the second most costly service ($\$1,226 \pm \$1,572$). Indirect costs comprised 31% of total costs. Participants were estimated to sustain a loss of $\$1,994 \pm \$6,905$ in work and $\$2,868 \pm \$3,761$ in school/housework related costs. No statistically significant between-group differences were noted in these baseline characteristics ($p > 0.05$).

Longitudinal Change: from Baseline (6 Months Pre-enrollment) to Follow-up (6 Months Post-enrollment)

Direct and Indirect Costs—Compared to baseline, both groups increased the number of medications used for conditions other than pain or constipation, and the total number of medications ($p < 0.05$; Table 2). Within-group changes in healthcare utilization and productivity were not statistically significant ($p > 0.05$; Table 2). However, the MM group

trended ($p=0.068$) toward reduced number of missed work days (Table 2) and related cost (Table 3), and controls showed a tendency ($p=0.083$) toward increased number of prescribed opioid medications (Table 2).

Between-group comparison of longitudinal changes did not show statistically significant differences in healthcare utilization, medication use and productivity loss (Table 2), and the related costs (Table 3). Evaluation of the Cohen's d effect size for between-group differences showed a promising yet statistically insignificant trend favoring the MM group over the control group at follow-up (Tables 2 & 3).

DISCUSSION

This secondary analysis showed that opioid-treated CLBP is associated with high direct and indirect costs, comprising 69% and 31% of total costs, respectively. Direct costs related to medications were high, constituting approximately 41% of all costs. Although our pilot RCT indicated that MM can reduce pain severity ratings and sensitivity to heat-pain stimuli,¹⁵ this analysis did not show a statistically significant impact of MM on direct or indirect costs.

A 2008 nationally-representative sample of patients with CLBP, the minority (37%) of whom were treated with any opioids, estimated total direct medical costs, including medications, to be $\$8,386 \pm 17,507$ annually, a figure that included CLBP-related surgeries, other procedures, and imaging,³ not accounted for in the current RCT. If our estimated 6-month healthcare utilization cost of $\$4,211 \pm 6,472$ was extrapolated to an annual figure, it would be comparable to that found in the above study;³ adding the cost of procedures and imaging to our calculations would likely result in costs surpassing the above estimates. The costs of medication and healthcare utilization are likely higher in opioid-treated populations with severe disability, such as the sample in the current study. Therefore, our study likely underestimates medical costs related to opioid-treated CLBP. In our study, the conservatively-estimated high cost related to opioid-treated CLBP is especially concerning because it was borne by a cohort whose income was, on average, low.

Although indirect costs were lower than direct costs in the current study, they were substantial and likely underestimated. Participants reported four times as many missed school/housework days than work days. The impact of school/housework loss likely translates to missed opportunities to engage in personal growth and positive activities with family or friends, and maintaining the household. The profound disease impact on work and school/housework was likely due to the severe level of disability reported by our participants, with only one-third ($N=15$) reporting paid employment.¹⁷ Since a missed day of work is cost-valued almost three times more than a missed day of school/housework, indirect costs depend heavily on employment characteristics; if more participants reported "being employed" but "unable to work," costs related to productivity loss would have increased. Restricting the sample to only those who reported paid work, the number of missed work days and related cost would double in this subsample to 28.6 ± 62.2 .

Despite high healthcare utilization and medication use at baseline, participant disability was high, indicating a reduced health-related quality of life. During 26-week follow-up, the MM

group, compared to controls, decreased their pain severity ratings (large effect size, $d=0.86$, $p=0.045$) and pain sensitivity to heat-pain stimuli ($p<0.05$),¹⁵ without increasing costs. Several trends may even suggest positive effects of the MM intervention on costs both for within-group changes (as suggested by $p<0.1$) and between-group differences (as suggested by effect size, Cohen's $d > 0.2$).

Limitations

This analysis was based on self-reported data, as opposed to claims or health system-based utilization data, thus introducing a possibility of reporting bias. Further, parameters used to calculate healthcare utilization costs were based on combined back, neck or spinal disorder diagnoses that may or may not have included individuals with opioid-treated CLBP. In addition, medication costs were extrapolated from a single month of data at baseline and two months of data post-entry, so they may not represent actual 6-month medication costs. Furthermore, our results were derived from a severely-disabled sample, so they may not extend to a less-affected population. Finally, because data on SSDI-based income were not collected, the effects of the MM intervention on SSDI-related costs are unclear. We elected not to include costs of the MM intervention delivery in our analysis. The benefits of sustained MM practice can persist well beyond the duration of the initial training,^{39,40} thus off-setting over a longer period the single-fee associated with the MM course.

Small sample size and short follow-up duration could have impacted the findings of this pilot study, which was likely underpowered for the conducted cost analysis. An adequately-powered trial, with sample size calculation enabled by the current pilot, is needed to determine the long-term effects of MM in this population. Incorporation of claims data and collection of detailed information on income and wages would enable a more conclusive evaluation of MM's impact on health-related cost in this patient population.

Conclusions

This study confirmed that adults with opioid-treated CLBP experience a high burden of disability despite high healthcare utilization, medication use and productivity loss related costs. Although MM shows promise for safely and effectively improving clinical outcomes in this population, this 26-week pilot RCT did not show a statistically significant impact of MM on costs related to opioid-treated CLBP, calling for further research in this area.

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Table 1

Baseline (6 months pre-enrollment) healthcare utilization, medication use and productivity loss reported by the study participants (N=35).

Variable (N=35)		
Healthcare Utilization	Number, #	Cost, USD
Outpatient Visits		
Primary Care		
Mean (SD)	7.1 (9.1)	\$1,226 (1,572)
Median (25–75%)	4.0 (2.0–6.0)	\$692 (346–1,038)
Urgent Care		
Mean (SD)	0.2 (0.5)	\$59 (141)
Median (25–75%)	0.0 (0.0–0.0)	\$0 (0–0)
Mental Health		
Mean (SD)	2.9 (5.2)	\$391 (704)
Median (25–75%)	0.0 (0.0–4.0)	\$0 (0–541)
Total Outpatient Visits		
Mean (SD)	10.2 (11.1)	\$1,675 (1,806)
Median (25–75%)	6.0 (4.0–12.0)	\$1,122 (692–2,076)
Emergency Department Visits		
Mean (SD)	0.5 (1.1)	\$459 (1,060)
Median (25–75%)	0.0 (0.0–1.0)	\$0 (0–945)
Days of Hospitalization		
Mean (SD)	1.2 (3.6)	\$2,075 (6,246)
Median (25–75%)	0.0 (0.0–0.0)	\$0 (0–0)
Total Healthcare Utilization		
Mean (SD)	----	\$4,211 (6,472)
Median (25–75%)		\$1,640 (865–4,672)
Medication Use	Number, #	Cost, USD
Opioid Medications		
Mean (SD)	1.8 (0.7)	\$1,254 (1,492)
Median (25–75%)	2.0 (1.0–2.0)	\$571 (338–2,012)
Non-Opioid Analgesics ^a and Pain-Modulating Medications ^b		
Mean (SD)	2.9 (1.7)	\$1,859 (2,489)
Median (25–75%)	3.0 (1.0–4.0)	\$373 (108–3,005)
Bowel Regimen Medications		
Mean (SD)	0.5 (0.8)	\$67 (180)
Median (25–75%)	0.0 (0.0–1.0)	\$0 (0–35)

Variable (N=35)		
Other Medications ^c		
Mean (SD)	7.9 (5.1)	\$3,243 (5,284)
Median (25–75%)	8.0 (4.0–12.0)	\$1,397 (338–3,436)
Total Medication Use		
Mean (SD)	13.1 (6.4)	\$6,423 (6,989)
Median (25–75%)	12.0 (8.0–19.0)	\$4,199 (1,241–8,511)
Productivity Loss	Number, #	Cost, USD
Days of Missed Work		
Mean (SD)	12.3 (42.4)	\$1,994 (6,905)
Median (25–75%)	0.0 (0.0–0.0)	\$0 (0–0)
Days of Missed School/Housework		
Mean (SD)	49.4 (64.8)	\$2,868 (3,761)
Median (25–75%)	18.0 (0.0–90.0)	\$1,044 (0–5,220)
Total Direct (Healthcare Utilization, Medications) and Indirect (Productivity Loss) Costs		
Total Direct Costs		
Mean (SD)		\$10,635 (9,897)
Median (25–75%)		\$7,426 (3,350–13,421)
Total Indirect Costs		
Mean (SD)		\$4,862 (7,298)
Median (25–75%)		\$1,740 (0–6,960)
Total Direct+Indirect Costs		
Mean (SD)		\$15,497 (13,677)
Median (25–75%)		\$10,851 (5,128–24,349)

Abbreviations: USD, United States Dollar

^a acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs).

^b GABA analogs, skeletal muscle relaxants, benzodiazepines, tricyclic antidepressants, serotonin and norepinephrine reuptake inhibitors (SNRIs), anti-epileptics and other medications reported for pain relief.

^c All other medications used for various medical conditions (e.g., hypertension, diabetes, depression), including over the counter ones (e.g., vitamins, supplements).

Table 2

Healthcare utilization, medication use and productivity loss among the study participants (N=35) by group status at baseline (6 months pre-enrollment) and 26 week follow-up (6 months post-enrollment).

	MM group (N=21)			Control group (N=14)			
Variable	Baseline	26 weeks	p value ^a	Baseline	26 weeks	p value ^a	Effect size Cohen's d (95% CI) ^c
Healthcare Utilization							
Number of Outpatient Visits:							
Primary Care							
Mean (SD)	7.1 (9.9)	8.0 (7.1)	0.230	7.1 (8.1)	9.3 (13.2)	0.279	0.14
Median (25–75%)	5.0 (3.5–5.5)	6.5 (2.9–10.4)		2.5 (2.0–11.3)	5.9 (1.5–10.8)		(−0.54; 0.82)
Urgent Care							
Mean (SD)	0.2 (0.5)	0.3 (0.6)	0.677	0.2 (0.6)	0.3 (0.6)	0.715	0.03
Median (25–75%)	0.0 (0.0–0.0)	0.0 (0.0–0.4)		0.0 (0.0–0.0)	0.0 (0.0–0.2)		(−0.65; 0.70)
Mental Health							
Mean (SD)	2.3 (4.6)	2.1 (4.0)	0.612	3.8 (6.1)	2.7 (4.1)	0.779	0.19
Median (25–75%)	0.0 (0.0–2.0)	0.0 (0.0–2.4)		1.0 (0.0–6.0)	0.0 (0.0–6.1)		(−0.87; 0.49)
Total Number of Outpatient Visits:							
Mean (SD)	9.6 (12.5)	10.3 (10.2)	0.357	11.1 (8.8)	12.3 (14.0)	0.975	0.05
Median (25–75%)	6.0 (3.5–11.5)	8.4 (2.9–13.4)		9.0 (3.8–19.5)	7.7 (2.1–19.2)		(−0.63; 0.72)
Number of ED Visits							
Mean (SD)	0.7 (1.4)	0.7 (1.1)	0.381	0.2 (0.6)	0.4 (1.0)	0.686	0.23
Median (25–75%)	0.0 (0.0–1.0)	0.0 (0.0–0.9)		0.0 (0.0–0.0)	0.0 (0.0–0.2)		(−0.45; 0.91)
Number of Days of Hospitalization							
Mean (SD)	1.6 (4.5)	0.6 (1.4)	0.463	0.6 (1.6)	0.1 (0.2)	0.285	0.11
Median (25–75%)	0.0 (0.0–0.0)	0.0 (0.0–0.0)		0.0 (0.0–0.0)	0.0 (0.0–0.0)		(−0.56; 0.79)
Medication Use							
Number of Opioid Medications							

Variable	MM group (N=21)			Control group (N=14)			p value ^b	Effect size Cohen's d (95% CI) ^c
	Baseline	26 weeks	p value ^a	Baseline	26 weeks	p value ^a		
Mean (SD)	1.9 (0.7)	2.0 (0.9)	0.414	1.6 (0.7)	1.9 (0.9)	0.083	0.702	0.24
Median (25–75%)	2.0 (1.0–2.0)	2.0 (1.0–2.5)		1.5 (1.0–2.0)	2.0 (1.0–2.3)			(–0.44; 0.92)
Number of Non-Opitoid Analgesics ^d and Pain-Modulating Medications ^e								
Mean (SD)	3.0 (1.6)	3.3 (1.7)	0.163	2.8 (1.8)	2.9 (1.9)	0.366	0.454	0.18
Median (25–75%)	3.0 (2.0–4.0)	3.0 (2.0–4.5)		2.5 (1.0–5.0)	2.5 (1.0–5.0)			(–0.85; 0.50)
Number of Bowel Regimen Medications								
Mean (SD)	0.5 (0.8)	0.6 (1.0)	0.083	0.6 (0.9)	0.5 (0.9)	0.157	0.727	0.79
Median (25–75%)	0.0 (0.0–1.0)	0.0 (0.0–1.0)		0.0 (0.0–1.0)	0.0 (0.0–1.0)			(–1.49; –0.09)
Number of Other Medications ^f								
Mean (SD)	8.1 (5.3)	10.3 (6.7)	0.009	7.4 (4.9)	9.9 (7.4)	0.008	0.881	0.10
Median (25–75%)	8.0 (4.5–12.0)	11.0 (4.0–15.0)		7.0 (2.8–12.3)	9.0 (2.8–16.3)			(–0.58; 0.78)
Total Number of All Medications								
Mean (SD)	13.5 (6.5)	16.2 (8.2)	0.006	12.5 (6.3)	15.2 (8.9)	0.004	0.654	0.00
Median (25–75%)	12.0 (8.5–18.5)	16.0 (9.5–22.0)		13.0 (5.8–19.0)	15.5 (8.3–20.3)			(–0.68; 0.68)
Productivity Loss								
Days of Missed Work								
Mean (SD)	19.6 (53.9)	0.5 (1.3)	0.068	1.3 (4.8)	0.3 (0.6)	1.000	0.987	0.43
Median (25–75%)	0.0 (0.0–3.5)	0.0 (0.0–0.0)		0.0 (0.0–0.0)	0.0 (0.0–0.2)			(–0.26; 1.11)
Days of Missed School/Housework								
Mean (SD)	39.6 (57.7)	28.1 (37.6)	0.654	64.2 (74.1)	34.9 (43.8)	0.152	0.829	0.25
Median (25–75%)	14.0 (0.0–61.0)	8.3 (2.5–48.2)		25.0 (0.0–135.0)	14.0 (1.5–67.8)			(–0.93; 0.43)

Abbreviations: ED: Emergency Department

^a Within group comparison (post-enrollment versus pre-enrollment); Related-Samples Wilcoxon Signed Rank Test

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q Between group comparison at the 26 week follow-up: Independent Samples Mann-Whitney U Test
 r Between group comparison of difference scores (post-enrollment versus pre-enrollment): Cohen's d, 95% Confidence Interval
 d acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs)
 e GABA analogs, skeletal muscle relaxants, benzodiazepines, tricyclic antidepressants, serotonin and norepinephrine reuptake inhibitors (SNRIs), anti-epileptics, and other medications reported for pain relief
 f Other medications used for various medical conditions (e.g., hypertension, diabetes, depression), including over the counter ones (e.g., vitamins, supplements)

Table 3

Costs (USD) related to healthcare utilization, medication use and productivity loss among the study participants by the group status at baseline (6 months pre-enrollment) and 26 week follow-up (6 months post-enrollment).

	MM group (N=21)			Control group (N=14)			
Variable	Baseline	26 weeks	p value ^a	Baseline	26 weeks	p value ^a	Effect size Cohen's d (95% CI) ^c
Costs Related to Healthcare Utilization							
Outpatient Visits							
Primary Care							
Mean (SD)	1,228 (1,706)	1,377 (1,220)	0.230	1,223 (1,410)	1,616 (2,286)	0.279	0.14
Median (25–75%)	865 (606–952)	1,130 (509–1,799)		433 (346–1,946)	1,022 (264–1,862)		(–0.54; 0.82)
Urgent Care							
Mean (SD)	61 (139)	71 (155)	0.677	55 (149)	70 (150)	0.715	0.03
Median (25–75%)	0 (0-0)	0 (0–94)		0 (0-0)	0 (0–43)		(–0.65; 0.70)
Mental Health							
Mean (SD)	309 (618)	283 (535)	0.612	512 (826)	362 (559)	0.779	0.20
Median (25–75%)	0.0 (0.0–271)	0 (0–320)		135 (0–812)	0 (0–824)		(–0.88; 0.48)
Total Costs Related to Outpatient Visits:							
Mean (SD)	1,598 (2,048)	1,730 (1,695)	0.375	1,791 (1,435)	2,049 (2,424)	0.975	0.07
Median (25–75%)	963 (606–1,859)	1,418 (509–2,251)		1,256 (694–3,231)	1,238 (369–2,957)		(–0.61; 0.74)
ED Visits							
Mean (SD)	630 (1,280)	615 (1,074)	0.381	203 (547)	415 (988)	0.686	0.23
Median (25–75%)	0 (0–945)	0 (0–831)		0 (0-0)	0 (0–186)		(–0.45; 0.91)
Hospitalization							
Mean (SD)	2,717 (7,744)	973 (2,392)	0.463	1,112 (2,846)	97 (364)	0.285	0.11
Median (25–75%)	0 (0-0)	0 (0-0)		0 (0-0)	0 (0-0)		(–0.56; 0.79)
Total Healthcare Utilization							
Mean (SD)	4,945 (7,880)	3,318 (3,446)	0.639	3,110 (3,441)	2,562 (3,176)	0.875	0.16

	MM group (N=21)			Control group (N=14)			
Variable	Baseline	26 weeks	p value ^d	Baseline	26 weeks	p value ^d	Effect size Cohen's d (95% CI) ^e
Costs Related to Medication Use							
Median (25–75%)	1,640 (994–4,737)	1,968 (509–5,059)		1,654 (775–4,755)	1,637 (369–2,957)		(–0.52; 0.83)
Opioid Medications							
Mean (SD)	1,356 (1,545)	1,253 (1,558)	0.149	1,102 (1,451)	1,487 (1,987)	0.510	0.69
Median (25–75%)	579 (366–2,129)	585 (278–1,870)		499 (196–1,194)	517 (194–2,572)		(–0.00; 1.39)
Non-Opioid Analgesics ^d and Pain-Modulating Medications ^e							
Mean (SD)	1,711 (1,794)	1,878 (1,923)	0.614	2,079 (3,342)	1,500 (2,207)	0.140	0.64
Median (25–75%)	614 (160–3149)	658 (150–3,412)		308 (59–3,212)	241 (60–2,518)		(–1.34; 0.05)
Bowel Regimen Medications							
Mean (SD)	89 (223)	104 (291)	0.678	34 (74)	26 (67)	0.753	0.35
Median (25–75%)	0 (0–84)	0 (0–60)		0 (0–21)	0 (0–21)		(–1.03; 0.34)
Other Medications ^f							
Mean (SD)	2,806 (4,501)	3,006 (4,888)	0.421	3,900 (6,409)	4,136 (6,544)	0.470	0.03
Median (25–75%)	932 (321–3,412)	1,025 (277–4,088)		1,985 (311–3,991)	2,072 (342–4,466)		(–0.65; 0.70)
Total Medication Use Costs							
Mean (SD)	5,962 (6,365)	6,241 (6,844)	0.794	7,115 (8,036)	7,149 (7,710)	0.826	0.12
Median (25–75%)	4,056 (2,030–7,348)	4,732 (2,293–6,572)		4,342 (964–12,249)	4,155 (925–10,849)		(–0.80; 0.56)
Costs Related to Productivity Loss							
Days of Missed Work							
Mean (SD)	3,185 (8,772)	84 (210)	0.068	209 (783)	48 (99)	1.000	0.43
Median (25–75%)	0 (0–570)	0 (0–0)		0 (0–0)	0 (0–34)		(–0.26; 1.11)
Days of Missed School/Housework							

Variable	MM group (N=21)			Control group (N=14)			p value ^d	Effect size Cohen's d (95% CI) ^e
	Baseline	26 weeks	p value ^d	Baseline	26 weeks	p value ^d		
Mean (SD)	2,297 (3,344)	1,628 (2,183)	0.654	3,724 (4,297)	2,026 (2,541)	0.152	0.829	0.25
Median (25–75%)	812 (0–3,538)	482 (146–2,797)		1,450 (0–7,830)	814 (85–3,932)			(–0.93; 0.43)
Total Direct (Healthcare Utilization, Medications) and Indirect (Productivity Loss) Costs								
Total Direct Costs								
Mean (SD)	10,907 (10,581)	9,559 (7,998)	0.986	10,226 (9,145)	9,711 (9,426)	0.594	0.678	0.12
Median (25–75%)	6,868 (4,859–11,846)	8294 (3,148–13,517)		8,997 (1,908–17,148)	6,314 (1,130–20,459)			(–0.80; 0.56)
Total Indirect Costs								
Mean (SD)	5,481 (8,826)	1,712 (2,140)	0.117	3,934 (4,234)	2,074 (2,511)	0.198	0.778	0.25
Median (25–75%)	1,369 (0–7,453)	836 (148–2,797)		2,914 (0–7,830)	940 (200–3,932)			(–0.43; 0.93)
Total Direct+Indirect Costs								
Mean (SD)	16,389 (15,459)	11,271 (8,368)	0.375	14,159 (10,880)	11,785 (9,960)	0.177	0.960	0.26
Median (25–75%)	10,271 (5,880–28,919)	10,111 (5,655–14,871)		14,287 (3,229–24,847)	10,266 (1,699–23,563)			(–0.94; 0.42)

Abbreviations: ED: Emergency Department; USD, United States Dollar

^aWithin group comparison (post-enrollment versus pre-enrollment): Related-Samples Wilcoxon Signed Rank Test

^bBetween group comparison at the 26 week follow-up: Independent Samples Mann-Whitney U Test

^cBetween group comparison of difference scores (post-enrollment versus pre-enrollment): Cohen's d, 95% Confidence Interval

^dacetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs)

^eGABA analogs, skeletal muscle relaxants, benzodiazepines, tricyclic antidepressants, serotonin and norepinephrine reuptake inhibitors (SNRIs), anti-epileptics, and other medications reported for pain relief

^fOther medications used for various medical conditions (e.g., hypertension, diabetes, depression), including over the counter ones (e.g., vitamins, supplements)